# Clinical Trials Data KIT - Document 66

# Clinical Validation of Lophius Biosciences Kit T-Track® CMV in Kidney Transplant Recipients

## Clinical Trial: https://clinicaltrials.gov/study/NCT02083042

"eligibilityCriteria": "Inclusion Criteria:\n\n\* Patient receiving a kidney graft\n\* Recipient being CMV-seropositive prior transplantation and receiving a graft from either a CMV-seropositive or from a seronegative donor (intermediate risk groups, D+/R+; D-/R+,)\n\* Patient scheduled to follow the preemptive antiviral strategy with oral valganciclovir or intravenous ganciclovir after transplantation\n\* Patient receiving the standard triple immunosuppressive regimen (CNI, MMF/MPA or mTOR inhibitors, steroids), with or without induction therapy (except ATG) as start therapy after transplantation\n\* Male or female patient at least 18 years of age\n\* Written informed consent\n\nExclusion Criteria:\n\n\* Patient is scheduled for the optional visit 1, but requires ongoing treatment with a systemic immunosuppressive drug already prior to kidney transplantation (except induction therapy other than ATG)\n\* Patient receiving ATG as induction therapy\n\* Patient is known to be positive for HIV or suffering from chronic hepatitis infections\n\* Patient has significant uncontrolled concomitant infections or other unstable medical conditions before transplantation that could interfere with the study objectives\n\* Patient is unable to comply with the visit schedule in the protocol\n\* Patient has any form of substance abuse, psychiatric disorder or condition that, in the opinion of the investigator may invalidate communication with the investigator",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
"stdAges": [  
"CHILD",  
"ADULT",  
"OLDER\_ADULT"  
],  
 "studyPopulation": "Kidney transplant recipients of intermediate risk groups for CMV serostatus (D+/R+; D-/R+), and scheduled for the preemptive antiviral strategy",

Question:  
Based on the following clinical trial information, would a patient with a KIT gene mutation be eligible for the clinical trial?

Answer:  
Based on the provided eligibility criteria for the clinical trial, there is no mention of KIT gene mutations as either an inclusion or exclusion factor. The eligibility criteria focus mainly on the patient's CMV serostatus, the type of antiviral and immunosuppressive treatments they will receive, and other general health and demographic requirements.  
  
Therefore, the presence of a KIT gene mutation would not affect a patient's eligibility for this clinical trial, as long as they meet all the other specified inclusion and exclusion criteria.